**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicants: | Vargas, Jaime; et. al. | | |
| Assignee: | Cardica, Inc. | | |
| Title: | Method for Sutureless Connection of Vessels | | |
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| Examiner: | Woo, Julian W. | Group Art Unit: | 3731 |
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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

# CORRECTED APPEAL BRIEF UNDER 37 CFR §41.37

This Corrected Appeal Brief is prepared and submitted pursuant to the Notice of Non-Compliant Appeal Brief mailed on March 20, 2008.

## I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardica, Inc., as named in the caption above.

## II. RELATED APPEALS AND INTERFERENCES

No pending appeals, interferences or other judicial proceedings, or prior interferences or other judicial proceedings, are known to Appellant, Appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by, or have a bearing on the decision by the Board of Patent Appeals in this appeal. No court or Board has rendered a decision pertaining to this patent application, and no such decisions can be provided in the Related Proceedings Appendix.

## III. STATUS OF CLAIMS

Claims 1-3 and 7-22 stand finally rejected, **and the rejection of these claims is expressly appealed**. These claims are set forth in the appendix attached hereto.

Claims 4-6 have been canceled, and as a result are not set forth in the appendix attached hereto.

## IV. STATUS OF AMENDMENTS

No amendments were filed after final rejection or are currently pending in this case.

## V. SUMMARY OF THE INVENTION

### A. Claim 1

Claim 1 is directed to a method of forming an anastomosis between a graft vessel (30) and a target vessel (32), each vessel (30, 32) having a lumen therein and a wall around the lumen, where that method comprises providing an anastomosis device (10, 40, 60, 80, 100, 120, 120', 120", 200, 220) and an expander (156); connecting an end of the graft vessel (30) to the anastomosis device (10, 40, 60, 80, 100, 120, 120', 120", 200, 220); delivering at least a portion of the anastomosis device (10, 40, 60, 80, 100, 120, 120', 120", 200, 220) into the lumen of the target vessel (32) through an opening (34) in the wall of the target vessel (32); manipulating the anastomosis device (10, 40, 60, 80, 100, 120, 120', 120", 200, 220) to form a first flange (20, 46, 66, 84, 114) therein, where the first flange (20, 46, 66, 84, 114) positioned in the lumen of the target vessel (32) and spaced apart from the wall of the target vessel (32), where the manipulating includes translating the expander (156) relative to the anastomosis device (10, 40, 60, 80, 100, 120, 120', 120", 200, 220), and where the manipulating completely forms the first flange (20, 46, 66, 84, 114); and moving the first flange (20,

46, 66, 84, 114) into contact with the wall of the target vessel (32) after the manipulating is complete.[1] Claims 2-3 and 7-22 depend from independent claim 1, and thus add additional limitations to those present in independent claim 1.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

### A. Claims 1-15

Independent claim 1 stands finally rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,461,320 to Yencho et. al. ("Yencho"). Dependent claims 2-3, 14, 15, 21 and 22 also stand rejected under Yencho. Independent claim 1 also stands finally rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,113,612 to Swanson et. al. ("Swanson"). Dependent claims 7-13, 16-20 and 22 also stand finally rejected under Swanson.

## VII. ARGUMENTS

### A. The Cited Art Does Not Anticipate the Claims

The MPEP sets forth the legal standard of anticipation under 35 U.S.C. §102: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[2] (emphasis added).

#### 1. Claims 1-15

Claim 1 claims "a method of forming an anastomosis between a graft vessel and a target vessel, each vessel having a lumen therein and a wall around the lumen." That method requires, among other steps, "providing an anastomosis device and an expander…manipulating said

[1] *E.g.*, Specification, page 7, line 14 through page 9, line 24; page 11, line 12 through page 14, line 23; page 15, line 2 through page 18, line 14; page 19, lines 4-19; Figures 1-11, 17-18, 23-29 (exemplary reference characters indicated in text above).

[2] MPEP 2131 (*quoting Verdegaal Brothers v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

anastomosis device to form a first flange therein, said first flange positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel; wherein said manipulating includes translating said expander relative to said anastomosis device, and wherein said manipulating completely forms said first flange; and moving said first flange into contact with the wall of the target vessel after said manipulating is complete." (emphasis added).

As the specification states, "advancing of the expander tube 156 increases the diameter of the anastomosis device 120 causing the first flange to fold outward from the device. The expanding of the first flange may be performed inside the vessel and then the device 120 may be drawn back until the flange abuts an interior of the target vessel wall 32."[3] Consistent with the specification, claim 1 requires manipulating the anastomosis device to "completely form[]" a first flange, and only then "moving said first flange into contact with the wall of the target vessel."

In contrast, Yencho describes moving a first flange into contact with the wall of the target vessel during formation of that first flange, rather than after that first flange is completely formed. The anastomosis device of Yencho is "longitudinally collapsed to position the flanges against the target vessel wall."[4] "During deployment of the distal end flange, the stent body longitudinally collapses, and the distal end flange is positioned at least in part within the wall of the target vessel."[5] That distal flange is not completely formed until it has reached its "final position," at which point the distal flange is in contact with the wall of the target vessel.[6] Both flanges of Yencho are created by rotating one end of the anastomosis device relative to the other, causing the anastomosis device to "longitudinally collapse as the helical members radially expand from the first to the second

[3] Specification; page 15, lines 21-25. (emphasis added).

[4] Yencho; col. 2, lines 60-64.

[5] *Id.*; col. 10, lines 61-63; Figures 18-19.

[6] *Id.*; col. 11, lines 1-5; Figure 19.

configuration."[7] That is, as torque is applied to the anastomosis device of Yencho to form the first flange, the distal end of the anastomosis device longitudinally collapses toward the wall of the target vessel as the helical members expand to form the first flange. As a result, as the first flange is being formed, the helical members move into contact with the wall of the target vessel, and when the first flange has been completely formed it is already in contact with the wall of the target vessel. Nowhere does Yencho describe, or even suggest, completely forming the first flange and only afterward moving that formed flange into contact with the target vessel.

Swanson also describes moving a first flange into contact with the wall of the target vessel during formation of that first flange, rather than after that first flange is completely formed. Upon inflation of a balloon 110, the connector of Swanson is annularly enlarged, and the second portion 40 of the connector 10 simultaneously flares out and moves proximally into contact with the wall of the conduit 300: "axial shortening of connector 10 that accompanies annular enlargement ensures that graft 120 is drawn into secure and fluid-tight engagement with conduit 300."[8] Indeed, Swanson describes that it is important to "ensure that the connector does not slip out of engagement with conduit 300 [*i.e.*, the target vessel] during annular enlargement of the connector."[9] Every embodiment of the connector of Swanson deforms in that manner, axially shortening as it annularly enlarges.[10]

The Office Action contends that Figure 10 discloses the distal portion of the graft vessel separating the wall of the target vessel from the first flange.[11] However, the second portion 40 of the connector 10 expands to form the first flange of Swanson, and "[s]econd portion 40 also includes a plurality of annularly spaced members 42 that in this case have free end portions 44 that are sharply

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[7] *Id.*; col. 10, lines 34-38.

[8] Swanson; col. 7, lines 61-63; *see* col. 11, line 54 through col. 12, line 7; Figures 9-10.

[9] Swanson; col. 12, lines 28-32 (emphasis added).

[10] Swanson; col. 10, lines 36-42.

pointed."[12] Figure 10 shows those members 42 – which are part of the second portion 40 of the connector by Swanson's express definition – not only in contact with the wall of the target vessel 300, but also penetrating into the wall of the target vessel 300.[13] When the first flange is in contact with the wall of the target vessel 300, as shown in Figure 10, it cannot simultaneously be "spaced apart" from the wall of the target vessel as required by claim 1. Turning to Figure 9, the members 42 are shown as spaced apart from the wall of the target vessel, but the first flange has not yet been formed in Figure 9, much less "completely formed" as required by claim 1.[14]

Both Yencho and Swanson describe connectors that shorten axially during the formation of a first flange, such that the first flange is only "completely formed" at such time that the first flange is in contact with the wall of the target vessel. Neither Yencho or Swanson expressly or inherently describe the claimed "manipulating [that] completely forms said first flange; and moving said first flange into contact with the wall of the target vessel after said manipulating is complete." Thus, Yencho nor Swanson expressly or inherently describes each and every element claimed in claim 1, and as a result claim 1 is believed to be in condition for allowance. Claims 2-3 and 7-22 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

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[11] Office Action, pages 3-4.

[12] Swanson; col. 5, lines 7-9.

[13] *Id.*; Figure 10.

[14] *Id.*; Figure 9.

## VII. CONCLUSION

For the above reasons, Applicants respectfully submit that the Final Action's rejection of pending claims 1-3 and 7-22 was unfounded. Accordingly, Applicants request that the rejection of those claims be reversed and that those claims be allowed.

Respectfully submitted,

/Brian A. Schar, Esq./

Brian A. Schar, Esq.
Reg. No. 45,076
Director of Intellectual Property
Cardica, Inc.
900 Saginaw Drive
Redwood City, CA 94063
(650) 331-7162

## APPENDIX 1 -CLAIMS

1. A method of forming an anastomosis between a graft vessel and a target vessel, each vessel having a lumen therein and a wall around the lumen; the method comprising:

providing an anastomosis device and an expander;

connecting an end of the graft vessel to said anastomosis device;

delivering at least a portion of the anastomosis device into the lumen of the target vessel through an opening in the wall of the target vessel;

manipulating said anastomosis device to form a first flange therein, said first flange positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel; wherein said manipulating includes translating said expander relative to said anastomosis device, and wherein said manipulating completely forms said first flange; and

moving said first flange into contact with the wall of the target vessel after said manipulating is complete.

2. The method of claim 1, wherein said connecting comprises everting an end of the graft vessel onto an end of said anastomosis device.

3. The method of claim 1, wherein said manipulating includes radially expanding at least a portion of said anastomosis device.

7. The method of claim 1, wherein said moving is substantially linear.

8. The method of claim 1, further comprising

providing a holder; and

connecting said anastomosis device to said holder, wherein at least a portion of said anastomosis device is separable from said holder.

9. The method of claim 8, wherein said moving is performed by moving said holder.

10. The method of claim 8, further comprising separating at least a portion of said anastomosis device from said holder after moving.

11. The method of claim 8, wherein said anastomosis device includes at least one tab at its proximal end, and wherein said connecting includes connecting at least one said tab to said holder.

12. The method of claim 1, further comprising manipulating said anastomosis device to form a second flange proximal to said first flange and positioned outside the target vessel.

13. The method of claim 12, wherein said second flange is at least partially in contact with the wall of the target vessel.

14. The method of claim 1, wherein said anastomosis device is at least partially tubular.

15. The method of claim 1, wherein said manipulating includes plastically deforming at least a portion of said anastomosis device.

16. The method of claim 1, wherein said anastomosis device is composed of stainless steel.

17. The method of claim 1, wherein said first flange includes a plurality of elements spaced apart from one another at their distal ends.

18. The method of claim 17, wherein said elements are arranged substantially radially symmetrically about the longitudinal axis of the anastomosis device.

19. The method of claim 17, wherein said connecting includes penetrating the graft vessel with at least one said element.

20. The method of claim 17, wherein said manipulating includes moving at least a portion of at least one said element away from at least a portion of a different said element.

21. The method of claim 1, wherein said anastomosis device is unitary.

22. The method of claim 1, wherein said translating comprises translating the distal end of said expander from a position within said anastomosis device to a position distal to and outside of said anastomosis device.

## APPENDIX 2 – EVIDENCE APPENDIX

None.

## APPENDIX 3 – RELATED PROCEEDINGS APPENDIX

None.